AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all previous listings and versions of claims in this application.

1. (Original) A system for transdermal delivery of an active therapeutic agent from a dried pharmaceutical composition comprising: an apparatus for facilitating transdermal delivery of an active therapeutic agent through skin of a subject, said apparatus capable of generating at least one micro-channel in an area on the skin of the subject, and a patch comprising at least one therapeutically active agent in a dried pharmaceutical composition.

2. (Original) The system according to claim 1 wherein the patch further comprises at least one layer selected from a backing layer, an adhesive and a microporous liner layer.

3. (Original) The system according to claim 1 wherein the dried pharmaceutical composition is hydrophilic.

4. (Original) The system according to claim 3 wherein the dried pharmaceutical composition comprises at least one hydrophilic therapeutically active agent.

5. (Original) The system according to claim 4 wherein the hydrophilic therapeutically active agent is selected from the group consisting of proteins, polypeptides, peptides, polynucleotides, oligonucleotides, growth factors, hormones, and salts thereof.

6. (Original) The system according to claim 5 wherein the hydrophilic therapeutically active agent is human growth hormone.

7. (Original) The system according to claim 5 wherein the hydrophilic therapeutically active agent is human insulin.

8. (Original) The system according to claim 4 wherein the dried pharmaceutical composition further comprises at least one additional hydrophilic agent.

9. (Original) The system according to claim 8 wherein the hydrophilic agent is mannitol.

10. (Original) The system according to claim 8 wherein the dried pharmaceutical composition comprises human growth hormone and mannitol.

11. (Original) The system according to claim 8 wherein the dried pharmaceutical composition further comprises a stabilizer.

12. (Original) The system according to claim 11 wherein the stabilizer is selected from carbohydrates, amino acids and polymers.

13. (Original) The system according to claim 12 wherein the carbohydrate is a disaccharide selected from sucrose and trehalose.

14. (Original) The system according to claim 11 wherein the pharmaceutical composition comprises human growth hormone, mannitol and sucrose.

15. (Original) The system according to claim 11 wherein the pharmaceutical composition comprises human growth hormone, mannitol and trehalose.

16. (Original) The system according to claim 1 wherein the active agent remains stable for at least three months at about 22°C.

17. (Original) The system according to claim 1 wherein the pharmaceutical composition further comprises at least one component selected from an anti-oxidant, a

buffering agent and a preservative.

18. (Original) The system according to claim 1 comprising an apparatus for facilitating transdermal delivery of a therapeutically active agent through skin of a subject, said apparatus comprising:

a. an electrode cartridge comprising at least one electrode; and

b. a main unit comprising a control unit which is adapted to apply electrical energy to the electrode when the electrode is in vicinity of the skin, typically generating current flow or one or more sparks, enabling to cause ablation of stratum corneum in an area beneath the electrode, thereby generating at least one micro-channel.

19. (Original) The system according to claim 18 wherein the electrode cartridge is removable.

20. (Original) The system according to claim 18 wherein the electrode cartridge comprises a plurality of electrodes capable of generating a plurality of micro-channels of uniform shape and dimensions.

21. (Original) The system according to claim 18 wherein the electrical energy is of radio frequency.

22. (Original) A printed patch comprising a dried pharmaceutical composition.

23. (Original) The printed patch according to claims 22 wherein the patch further comprises at least one layer selected from a backing layer, an adhesive and a microporous liner layer.

24. (Original) The printed patch according to claim 22 wherein the dried pharmaceutical composition is hydrophilic.

25. (Original) The printed patch according to claim 24 wherein the dried pharmaceutical composition comprises at least one hydrophilic therapeutically active agent.

26. (Original) The printed patch according to claim 25 wherein the hydrophilic therapeutically active agent is selected from the group consisting of proteins, polypeptides, peptides, polynucleotides, oligonucleotides, growth factors, hormones, and salts thereof.

27. (Original) The printed patch according to claim 26 wherein the hydrophilic therapeutically active agent is human growth hormone.

28. (Original) The printed patch according to claim 26 wherein the hydrophilic therapeutically active agent is human insulin.

29. (Original) The printed patch according to claim 25 wherein the dried pharmaceutical composition further comprises at least one additional hydrophilic agent.

30. (Original) The printed patch according to claim 29 wherein the hydrophilic agent is mannitol.

31. (Original) The printed patch according to claim 29 wherein the dried pharmaceutical composition comprises human growth hormone and mannitol.

32. (Original) The printed patch according to claim 29 wherein the dried pharmaceutical composition further comprises a stabilizer.

33. (Original) The printed patch according to claim 32 wherein the stabilizer is selected from carbohydrates, amino acids, and polymers.

34. (Original) The printed patch according to claim 33 wherein the carbohydrate is a disaccharide selected from sucrose and trehalose.

35. (Original) The printed patch according to claim 32 wherein the dried pharmaceutical composition comprises human growth hormone, mannitol and sucrose.

36. (Original) The printed patch according to claim 32 wherein the dried pharmaceutical composition comprises human growth hormone, mannitol and trehalose.

37. (Original) The printed patch according to claim 22 wherein the active agent remains stable for at least three months at about 22°C.

38. (Original) The printed patch according to claim 22 wherein the pharmaceutical composition further comprises at least one component selected from an anti-oxidant, a buffering agent and a preservative.

39. (Original) The system according to claim 1 wherein the patch comprises a dried pharmaceutical composition.

40. (Original) A method for transdermal administration of a dried pharmaceutical composition comprising a therapeutically active agent comprising:

(a) generating at least one micro-channel in an area of the skin of a subject, and

(b) affixing a patch comprising a dried pharmaceutical composition comprising at least one therapeutically active agent to the area of skin in which the micro-channels are present.

41. (Original) The method according to claim 40 which further comprises:

(c) achieving a therapeutic blood concentration of the active agent for a predetermined period of time.

42. (Original) The method according to claim 40 wherein the dried pharmaceutical composition is hydrophilic.

43. (Original) The method according to claim 42 wherein the dried pharmaceutical composition comprises at least one hydrophilic therapeutically active agent.

44. (Original) The method according to claim 43 wherein the hydrophilic therapeutically active agent is selected from the group consisting of proteins, polypeptides, peptides, polynucleotides, oligonucleotides, growth factors, hormones, and salts thereof.

45. (Original) The method according to claim 44 wherein the hydrophilic therapeutically active agent is human growth hormone.

46. (Original) The method according to claim 45 wherein the predetermined period of time is about 1 to 6 hours.

47. (Original) The method according to claim 44 wherein the therapeutically hydrophilic active agent is human insulin.

48. (Original) The method according to claim 47 wherein the predetermined period of time is about 4 to 6 hours.

[[48]] 49. (Currently Amended) The method according to claim 40 wherein the patch is a printed patch comprising a dried pharmaceutical composition.

[[49]] 50. (Currently Amended) A method for preparing a printed patch comprising a therapeutically active agent comprising:

a. preparing a pharmaceutical solution or suspension comprising at least one therapeutically active agent;

b. placing at least one measured volume of the solution or suspension of (a) on a suitable matrix; and

c. drying the matrix of (b) by drying means, which maintain the therapeutic activity of the therapeutically active agent of (a).

51. (New) The system according to claim 1 wherein the patch comprises at least two electrodes integrated thereto.

52. (New) The system according to claim 1 wherein the apparatus comprises a transport facilitation unit comprising electrodes which are adapted to induce iontophoresis of the at least one therapeutically active agent into the skin of the subject.

53. (New) The method according to claim 40 wherein the patch comprises at least two electrodes integrated thereto.

54. (New) The method according to claim 40 comprising inducing iontophoresis of the at least one therapeutically active agent into the skin of the subject.

55. (New) The method according to claim 54 wherein inducing the iontophoresis comprises inducing the iontophoresis subsequent to the generating of the at least one micro-channel.